



December 1, 1997

1518 '98 FEB 18 A8

12/9/97

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 "C"Street SW Washington, DC 20204

Section 403(r)(6) Notification

Dear Sir or Madam:

In response to the courtesy letter received on November 19, 1996 from the FDA, suggesting that our previous statement for this product was a drug claim, **LEINER HEALTH PRODUCTS** notifies FDA that it is resubmitting the following restructured statement in accordance with the requirements of section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act:

Pyruvate helps regulate the body's metabolic processes to nutritionally achieve and support an ideal body weight.

on the following product:

Your Life® Natural Pyruvate with Chromium Picolinate

Very truly yours,

LEINER HEALTH PRODUCTS

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs William Cochran, Regulatory Affairs

975-0162

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